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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/30/2003

C9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/084,832	ABDELOUAHED ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1--37* is/are pending in the application.

4a) Of the above claim(s) *8-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 34-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's response to the Office Action mailed June 19, 2003 (Paper #12) is acknowledged. Currently, claims 1-7 and 34-37 are pending and claims 1-2 has been amended. Claims 8-33 has been withdrawn from considereation.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Jean Amiral as evidenced by Thorpe et al (USP#6,312,694).

Jean Amiral discloses an isolated complex that includes heparin binding proteins platelets (col. 4, line 31). These platelets proteins are antigenic fractions that are lysed from blood platelets and have a strong affinity for heparin that can induce anti-heparin antibodies (col. 5, lines 13-29). The drug heparin is mixed with a complex of antigenic substances to determine the presence of antibodies (see summary). Heparin binding proteins were isolated from mammalian blood during clinical trials (col. 11, lines 10-35). Although Jean Amiral does not particularly point out what the platelet proteins are, evidence is provided by Thorpe et al, that thrombospondin-1 and platelet factor 4 are found in platelet alpha granules and are known to associate with heparin (See

USP#6,312,694, col. 99, lines 47-50). Jean Admiral discloses that heparin bind to platelet complexes, therefore it is inherent that thrombospondin-1 and platelet factor 4 will be included in that complex. Jean Amiral also discloses an assay kit to determine a heparin-induced thrombopenia (col. 10, lines 10-67). The platelet factor 4 and thrombospondin-1 are present at a ratio determined to be optimal for recognition especially since Thorpe et al discloses that these heparin binding proteins associated with heparin. Claims 6 and 7 will not be given patenable weight because the claims are drawn to a method of making the product.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Gogstad et al (British Journal of Haematology, Apr 1983, Vol. 53, (4), pages 563-73)

Gogstad et al teaches a complex of platelet proteins that were isolated from alpha-granules. These platelet proteins comprise of platelet factor 4 and thrombospondin bound to immobilized heparin. Platelet proteins were applied to crossed immunoelectrophoresis against anti-platelet antibodies (see whole abstract).

Patenable weight will not be given to claims 6 and 7 because the claims are drawn to a method of making the product.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jean Amiral as evidenced by Thorpe et al in view of Zuk et al (USP#4,281,061).

The teachings of Jean Amiral as evidenced by Thorpe et al are set forth above and differ from the instant claims in not teaching all the components of a kit.

However, Zuk et al teaches that "as a matter of convenience the reagents of an immunoassy can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (col. 22, lines 63-66).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take reagents such as the anti-hep antibody and the heparin binding proteins as taught by Jean Amiral and evidenced by Thrope et al and formulate them into a kit because Zuk et al teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the

reagents in a kit are available in pre-measured amounts, which can eliminate the variability that can occur when performing the assay.

Response to Arguments

8. Applicant's arguments filed September 23, 2003 have been fully considered but they are not persuasive.

Applicant's argument the reference of Jean Amiral described complexes PF4 and heparin but did not include TSP-1 into any complexes with heparin is not found persuasive. The instant claims are broadly drawn to an isolated complex that includes three elements: heparin, platlet factor 4 (PF4) and thombospodin (TSP-1). The instant claims does not establish how these elements are bound together, therefore the claims are viewed in its broadest interpretation. The reference of Jean Amiral describes a freezed platelet lyzate, which is washed, thawed and contacted with an aqueous solution forming a precipitate. The supernate is collected, dialyzed and deposited on a column of heparin-agarose gel. Fractions of PF4 and thrombospondin were found on heparin-argarose gel and later separated. The reference of Jean Amiral also teaches that heparin binds to blood platlets; and as evidence by Thorpe et al, heparin binding proteins are found in platlet a-granules and are known to associate with heparin.

Applicant's argument that the Thorpe et al reference gave no evidence concerning TSP-1 and PF4 being known to associate with heparin in a single ternary complex comprising heparin is not found persuasive. The reference of Thorpe et al disclosed that TSP-1 and PF4 are both angiogenesis inhibitors that associate with

heparin and are found in platelet a-granules (colum 99, lines 47-50). With respect to TSP-1 and PF4 binding in a single ternary complex is a limitation not found in the claims.

Applicant's argument that the assay kit taught by Jean Amiral does not contain TSP-1 is not found persuasive because the instant reference teaches isolated thrombospondin which can be incorporated into a kit format.

Applicant's argument the Gogstad et al reference do not teach a complex comprising heparin, PF4, and TSP-1 and there is not evidence of these elements binding together in a soluble complex at the same time and under the same conditions is not found persuasive. The Gogstad et al reference teaches isolated alpha-granules containing PF4 and TSP-1 contacted with immobilized heparin (see page 569). With respect ***to binding together in a soluble complex at the same time and under the same conditions*** are limitations not found in the claims.

Applicant's argument that the reference of Godstad et al does not discuss anything about heparin, PF4 and TSP-1 forming a ternary complex are not found persuasive because they contain limitations that are not found in the instant claims.

Applicant's argument that the reference of Jean Amiral as evidenced by Thorpe et al do not include components of the kit is not found persuasive. Although the instant kit taught by Jean Amiral does not include TSP-1, this element is still taught in the reference (column 9, lines 45-50). It would have been obvious to one of ordinary skill in the art to construct the reagent components in a kit format, especially since the reference of Zuk et al teaches that it is a matter of convenience for the reagents of an

immunoassay to be provided as kits because they come in predetermined ratios so as to substantially optimize the sensitivity of the assay in the range of interest (see Zuk et al, column 22, lines 63-66). Therefore it is the Examiner's position that the instant references read on applicant's invention and the rejections above are maintained.

Conclusion

9. No claims are allowed.

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Deborah A. Davis
CM1, 7D16
December 18, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
12/26/03